510(k) Summary

In accordance with the requirements of 21 CFR §807.92 the following summary of 510(k) safety and effectiveness information for the Ziehm Vision FD is being submitted.

K061534

Date:

May 29, 2006

JUL - 7 2006

Name of Submitter:

Ziehm Imaging, Inc.
4181 Latham Street
Riverside, CA 92501
(951) 718-2020

Corresponding Official:

Richard Westrich,
V.P. Product Development, Regulatory Affairs

Device Proprietary Name:

Ziehm Vision FD Digital Mobile Imaging System

Classification Name:

System, X-ray, Fluoroscopic, Image-Intensified

Solid State X-ray Imager (flat panel/digital imager)

Common/Usual Names:

Digital Mobile Imaging System

Fluoroscopic Imaging System

Digital Mobile C-arm,

Substantial Equivalence:

The ZIEHM VISION FD product does not raise new questions of safety or effectiveness and is substantially equivalent to the following current legally marketed devise ZIEHM VISION.

- Ziehm Imaging, Inc. ZIEHM VISION Digital Mobile Imaging System 510(k) K011292

The device is a mobile C-arm type x-ray system intended for fluoroscopic imaging. The systems include high-voltage x-ray generator, and control, fixed anode x-ray tube, image intensifier, touch control user interface and monitor cart/workstation with video image displays, digital image processing and image storage capabilities.

Device Description:

Indications for Use

The Ziehm Vision FD is intended to provide pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. Is intended for use in visualizing complex anatomical structures and procedures such as, vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, critical care, emergency room procedures, and where higher accuracy in image geometry is required. At the discretion of a physician the device may be used for other imaging applications.

User Characteristics

The device is intended for use by health care professionals such as physicians, surgeons, cardiologists, radiologists and technologists in hospitals, out-patient clinics and other clinical environments. Ziehm Imaging anticipates the device will be used on a nearly daily basis. Ziehm Imaging applications specialists and/or qualified site personnel provide on site operator training in the proper use of the device.

General Description

The ZIEHM VISION FD has two main units; Mobile Stand and Monitor Cart workstation. The Mobile Stand C-arm consists of a high frequency generator, X-ray Tube assembly, Solid State X-Ray Imager / Flat Panel Detector, user touch control interface, C-Profile supporting the generator and Solid State X-ray Imager (SSXI), and Integrated Laser light localizers in the image receptor. The Mobile Stand C-profile provides fixed distance mounting of the generator and image receptor allowing the user rotational and linear movements for positioning the c-arm at various angles and distances for visualization of patient's anatomical structures.

The monitor cart workstation supports dual flat panel LCD display monitors, Vision II digital image memory device, imaging capture, image processing, and VisionCenter touch control user interface. External Video connection is provided with RS-170 video timing for domestic market, CCIR for International markets. The Vision FD also provides optional peripheral connections for such devices as video printers, DICOM 3 and external media storage devices.

Standards:

The ZIEHM VISION FD series mobile x-ray systems were designed to comply with applicable portions of the following standards and regulations for product safety requirements:

- Federal Performance Standard for Diagnostic X-ray Systems 21 CFR 1020.30, 21 CFR 1020.31 and 21 CFR 1020.30
- UL 60601-1 Medical Electrical Equipment
- IEC 6060'1-1, Medical Electrical Equipment, General Requirements for Safety
- IEC 60601-1-2, Medical Electrical Equipment, General Requirements for Safety, Electromagnetic Compatibility
- IEC 60601-1-3, Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment
- IEC 60601-1-4, General requirements for safety, Programmable electrical medical systems.
- IEC 60601-2-7, Medical Electrical Equipment, Safety of HV/X-ray Generators
- IEC 60601-2-28, Medical Electronic, Particular Requirements for Safety of X-ray Source Assemblies, and X-ray Tube Assemblies.
- IEC 60601-2-32, Medical Electrical Equipment, Safety of Associated X-ray Equipment
- IEC 60825-1, Safety of Laser Products, Equipment Safety , Requirements, and User Guide
- 93/42/EEC - Annex 1 Essential Requirements of the Medical Devices Directive
- DIN ISO 14971

Conclusion:

The ZIEHM VISION FD does not raise new questions of safety or effectiveness and is substantially equivalent to the current model Ziehm Vision with image intensifier K011292.

End of 510(k) Summary

Richard Westrich
Vice President Product Development and Regulatory Affairs
Ziehm Imaging, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL - 7 2006

Mr. Richard Westrich
Vice President of Product Development and Regulatory Affairs
Ziehm Imaging, Inc.
4181 Latham Street
RIVERSIDE CA 92501

Re: K061534
Trade/Device Name: Ziehm Vision FD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: May 29, 2006
Received: June 2, 2006

Dear Mr. Westrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ziehm imaging

Indications For Use Statement:

Applicant: Ziehm Imaging, Inc.

510(k) Number (if known): K061534

Device Name: ZIEHM VISION FD

Intended Use: The Ziehm Vision FD is intended to provide pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. Is intended for use in visualizing complex anatomical structures and procedures such as, vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, critical care, emergency room procedures, and where higher accuracy in image geometry is required. At the discretion of a physician the device may be used for other imaging applications.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061534

Ziehm Imaging, Inc. an Ziehm Imaging GmbH Division
4181 Latham Street • Riverside CA. 92501 USA • Tel. 951-781-2020 • Fax 951-781-6457
http://www.Ziehm.com